510(k) Summary

AUG - 9 2010

This summary of 510(k) safety and effectiveness information is updated citing K092830, DRC-1000, digital X-ray imaging system as a predicate and the device is a subset of components of the K092830, DRC-1000 digital X-ray imaging system with the same technological characteristics in accordance with requirements of 21 CFR Part 807.92.

Date: July 23, 2010

1. Company and Correspondent making the submission:

Name – E-Woo Technology Co., Ltd.
Address – 1F, 4F, Yunmin Technotown 473-4 Bora-Dong, Giheung-Gu, Yong in-Si, Gyeong gi-Do, Korea, 446-904
Telephone – +82-31-673-2093
Fax – +82-31-377-1882
Contact – Mr. Jason Park / Assistant Manager
Internet – http://www.e-wootech.com

2. Device :

Trade/proprietary name	: Xmaru1717
Common Name	: Digital Flat Panel X-Ray Detector
Classification Name	: Solid State X-ray Imaging Device

3. Predicate Devices :

Manufacturer	: Canon Inc.
Device	: CXDI-50G
510(k) Number	: K031447 (Decision Date - May. 21. 2003)
Manufacturer	: Vatech Co. Ltd
Device:	: DRC-1000, Digital X-ray Imaging System
510(k) Number	: K092830

4. Classifications Names & Citations :

21CFR 892.1650, MQB, Solid State X-ray Imaging Device, Class2

5. Description :

5.1 General

Xmaru1717 is the TFT-based Flat Panel X-Ray Detector that keeps this Digitally based World going forward by providing the most important solution converting transmitted X-Ray into Digital Information.

Xmaru1717 is a medical image processing unit. Especially, advanced digital imaging process allows considerably efficient diagnosis, all kind of information management, real-time sharing of image information on network.

5.2 Product features

Xmaru1717 is an X-Ray image acquisition device that is based on flat-panel. This device should be integrated with an operating PC and a X-Ray generator. It can do to utilize as digitalizing x-ray images and transfer for radiography diagnostic

6. Indication for use :

Xmaru1717 Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.

7. Comparison with predicate device :

E-Woo Technology Co., Ltd., believes that the Xmaru1717 is substantially equivalent to the CXDI-50G of Canon Inc. and the device is a subset of components of the K092830, DRC-1000 digital X-ray imaging system from Vatech Co. Ltd, with the same technological characteristics in accordance

8. Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1 was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2001). All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification E-Woo Technology Co., Ltd. concludes that The Xmaru1717 is safe and effective and substantially equivalent to predicate devices as described herein.

10. E-Woo Technology Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

E-Woo Technology
% Mr. Vincent Lee
Official Correspondent
E-Woo Technology USA, Inc.
256 N. Sam Houston Pkwy E. Suite 115
HOUSTON TX 77060

AUG 23 2013

Re: K091090
Trade/Device Name: Digital Flat Panel X-Ray Detector/Xmaru1717
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: December 22, 2009
Received: December 28, 2009

Dear Mr. Lee:

This letter corrects our substantially equivalent letter of August 9, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

K091090

510(k) Number(if known): K091090

AUG - 5 2010

Device Name: Digital Flat Panel X-Ray Detector /Xmaru1717

Indications for Use:

Xmaru1717 Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K091090